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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte OLEG LLIICH EPHSTEIN

Appeal No. 2010-010242
Application No. 09/117,838
Technology Center 1600

Oral Hearing Held: November 9, 2011

Before ERIC GRIMES, STEPHEN G. WALSH and MELANIE L. McCOLLUM, *Administrative Patent Judges*.

APPEARANCES:

ON BEHALF OF THE APPELLANT:

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33 The above-entitled matter came on for hearing on Wednesday,
34 November 9, 2011, commencing at 2:49 p.m., at the U.S. Patent and
35 Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Paula
36 Lowery, Notary Public.

PROCEEDINGS

THE USHER: Good afternoon. Calendar Number 25, Appeal Number 2010-010242, Mr. Pergament.

JUDGE GRIMES: Good afternoon, Mr. Pergament. We have one of our judges, Judge Walsh, who's participating by video conference today. There is a bit of an audio delay going back and forth, so let him finish the question before you start to answer, if you would.

MR. PERGAMENT: Understood.

10 JUDGE GRIMES: If you would introduce your guest for the record,
11 we would appreciate it.

12 MR. PERGAMENT: Sure, this is Ms. Daria Reznickenko. She's
13 head of IP for -- Medical Holdings and Dr. Ephstein, the Applicant.

14 JUDGE GRIMES: You have 20 minutes to make your argument, and
15 you can get started when you're ready.

16 MR. PERGAMENT: May it please the Board, I'd like to begin with a
17 little bit of a conceptual issue as to what this invention is all about to provide
18 some background before addressing some of the legal arguments and getting
19 into details.

20 The Applicant, Dr. Ephstein, has made the discovery. I'd like to think
21 that was explained and discussed in the Appeal Brief and Reply Brief to the
22 Board.

23 The discovery is summarized in that the homeopathic form of a
24 substance, in other words a form of a substance that's obtained by dilution of
25 the neutral

1 substance, the substance has been diluted multiple times consecutively in
2 accordance with homeopathic technology.

3 When it is mixed with a normal standard formula substance, modifies
4 the properties of the original standards of the substance. It's a fundamental
5 discovery that Dr. Ephstein has shown applicable across the board in the
6 physical world as well as the chemical world and biological world, and
7 without that background it's difficult to address the merits of the claims.

8 The nature of this interaction, the reason for why it happens, as often
9 happens is not necessarily self-evident; but the effects of what is occurring
10 manifests itself in various mediums both in the physical world and in the
11 chemical world. That's where I want to begin because without this the
12 merits of the claim will not be clear.

13 On February 7, 2008, we have submitted the declaration of Dr.
14 Ephstein, which included a variety of data. We don't ask the Board to
15 believe on our words. We have all the data, a wide range of data. Biological
16 data, physical data, data in vitro, data in vivo -- they all boil down to the
17 properties of a substance that's been obtained in the same manner.
18 The homeopathic form of substance being mixed with the standard form of
19 the substance. Then that mixture being compared to the properties of the
20 standard form of the substance.

21 In every instance it was discovered that the properties are different.
22 The modified form of substance have different properties in a variety of
23 ways.

1 As an example, in Paragraph 6 of the declaration it was found that
2 inflammatory effect of prednisone, which is a well-known anti-inflammatory
3 agent, was enhanced in a statistically significant manner.

4 So if you compare the anti-inflammatory effect of prednisone without
5 any treatment with homeopathic form, it has certain activity, and then you
6 compare it with treated prednisone, the anti-inflammatory effect increases.
7 The analgesic effect of prednisone shows exactly the same effect.

8 In purely physical world, we have shown in declaration that a physical
9 hydrolysis of the -- acid, which is a standard physical process, chemical
10 process -- was reduced by 12.5 percent when it was treated with
11 homeopathic form.

12 Co-administration of isolated ethanol, which is a standard substance,
13 with homeopathic form of ethanol have changed the activity of the --
14 JUDGE MCCOLLUM: Can I ask a question? Isolated administration, for
15 example in Paragraph 14, it's isolated ethanol administration -- what does
16 that mean exactly?

17 I was having trouble understanding exactly what was being compared
18 to what, and you used the terms "isolated administration" or "isolated
19 ethanol administration". Does that mean ethanol by itself? Does that mean
20 a 5 percent ethanol solution? Those are two possibilities that came to mind.

21 MR. PERGAMENT: There are, I would readily admit, deficiencies in
22 details and exact use of experiments that have been presented in the
23 declaration, okay. I have to stay within the record as it is.

24 Referring to Paragraph 14, the inhibition of alcohol was measured by
25 ethanol alone and compared with the same property when ethanol was

1 pretreated with C200 homeopathic dilution of ethanol. The difference was
2 significant -- with P value of -- which is statistically significant.

3 I would love to have information about more detail about this
4 experiment. It was 5 percent ethanol solution for ethanol alone and 5
5 percent --

6 JUDGE MCCOLLUM: You're saying isolated ethanol administration
7 means ethanol alone.

8 MR. PERGAMENT: Ethanol alone.

9 JUDGE MCCOLLUM: Not a 5 percent ethanol solution. So that's far
10 more concentration-wise, a far greater amount of ethanol than what it's being
11 compared to.

12 MR. PERGAMENT: Again, I would wish this -- I have come to the
13 record the way it is. I would rather have more clarity on this, but I assure
14 you 5 percent ethanol solution was used before the homeopathic form was
15 added, and 5 percent ethanol solution was used when homeopathic form was
16 added. Apples were compared to apples.

17 JUDGE MCCOLLUM: Okay, so isolated ethanol administration does
18 not mean --

19 MR. PERGAMENT: Isolated in this particular instance means
20 ethanol without addition of homeopathic form.

21 JUDGE MCCOLLUM: Okay.

22 MR. PERGAMENT: Notwithstanding admitted -- I wouldn't call it
23 deficiencies, but certain amount of inexactitude in some of the experiments,
24 the sheer volume of experiments across the board shows the effect exists.

25

1 JUDGE MCCOLLUM: This problem seems to occur in most, if not
2 all -- it's not really clear what's being compared. If I'm going to make some
3 conclusions to it, how do I make any conclusions when I can't tell what's
4 being compared?

5 MR. PERGAMENT: With your permission, if we look at the
6 paragraph -- I'd like to make some legal arguments, but it does boil down to
7 data, and I have to agree with the Board on this.

8 If we look at Paragraph 20, and we show one there --

9 JUDGE MCCOLLUM: Which paragraph?

10 MR. PERGAMENT: Paragraph 20 of the declaration. I'm taking it
11 without any particular specific selection.

12 Walker 256 model tumor cells were transplanted into mice subcutaneously
13 at .2 milliliters of 20 percent salt solution was added to show that three times
14 the -- resulted in two-fold reduction of tumor mass. The number of
15 metastasis decreased by 30 percent as compared to isolated administration
16 using the same scheme.

17 In other words, notwithstanding imperfect extraction of this, what the
18 data have been presented is saying the metastasis has been reduced by 30
19 percent if you compare administration of cyclosporin treated with hepatic
20 cyclosporin, compared with cyclosporin alone.

21 That's the data that I'm presented with in here. If we look at
22 Paragraph 7: The ultra-low dose of prednisone C-12, C-30 or C-200 -- those
23 are a mixture of homeopathic solutions -- enhance the analgesic properties of
24 prednisone in a dose of 53 mg in a model of -- to combine the administration
25 of prednisone and ultra-low dose of prednisone caused the reduction in the

1 number by 30 percent with P value of less than 1025, which is statistically
2 significant.

3 In pain sensitivity, as compared to an isolated administration of
4 prednisone, isolated administration of prednisone means administration of
5 prednisone alone without a mixture of the homeopathic form of prednisone.
6 In each and every case, notwithstanding imperfect expression which I have
7 to concede, the comparison was between a form of the substance in
8 therapeutic dose or in the normal form and a form of the substance that was
9 strictly homeopathic form.

10 So from the legal standpoint, anticipation requires that every
11 requirement has been met. The Examiner's position, if I may summarize it,
12 is this: homeopathic form has nothing in it. In other words, it's a complete
13 dilution. So when you add homeopathic form to the standard form, you have
14 the same form as it was before.

15 If there was no data that shows that is not the fact, this would be
16 understandable. Otherwise, the Examiner simply ignores the express
17 language of the claims.

18 My client is not looking to infringe on what's going to use standard
19 therapeutic form of substances. If the standard therapeutic form of
20 substances was not treated with homeopathic form, there would be no
21 infringement.

22 If there was no medication on either side of the profile or efficacy in
23 comparison with the standard known therapeutic effects of efficacy of form,
24 then this would not infringe.

1 We're only looking to claim a new form of a substance. The data
2 showed it does exist. The effect does manifest itself across the board in
3 various environments.

4 The claim also have been amended to not just require a combination
5 of a therapeutic dose and homeopathic dose, but only a combination in
6 which there is enhanced therapeutic efficiency, which is manufactured either
7 in better side effect profiles or enhanced efficacy.

8 So it's not in every case that treatment with homeopathic form is going
9 to reduce this effect. We're only claiming those situations where this effect
10 is observed, okay?

11 The inventor has done a large number of experiments, shows the
12 effect is there. The record is in the file record. There is no contrary record,
13 and we're asking the Board to basically look at the law and say, well, data is
14 there and data in the record. We're asking the Board to believe the data.

15 JUDGE MCCOLLUM: Does homeopathic form require any
16 particular solvent that you do the dilution with? Is it water? Could it be any
17 solvent? Is the claim open to dilution with anything?

18 MR. PERGAMENT: The art of homeopathic is a well-established
19 and well-known art. Typically, water, ethanol, or ethanol solution is used
20 for dilution.

21 JUDGE MCCOLLUM: Okay.

22 MR. PERGAMENT: There is a document which is, again, well
23 established in the art from the German pharmacopeia, American
24 homeopathic pharmacopeia, British homeopathic pharmacopeia, so the

1 meaning of the word "homeopathic form of substance" is well known. It's a
2 substance that's going to have homeopathic potency.

3 It has to be multiple consecutive dilutions, coupled with some sort of
4 external effect, either shaking -- it's well known, well established in the
5 homeopathic art.

6 JUDGE MCCOLLUM: Looking particularly at Claim 23, if a solvent
7 in any way -- a non-homeopathically produced solvent -- enhanced the
8 therapeutic properties of an agent or of an active medicinal substance, how
9 would that distinguish from Claim 23?

10 I know it says that it requires the homeopathic dilution -- maybe my
11 question is not making sense. Never mind.

12 I'm just worried if there's something else that you put in there that
13 somehow potentiates the -- never mind.

14 MR. PERGAMENT: With your permission I will answer that. The
15 term "of homeopathic" has a well-established meaning in the homeopathic
16 art. It requires multiple, consecutive dilutions until homeopathic potency is
17 achieved. It's a 200 year old art that has been well established.

18 Interestingly enough, the efficacy of homeopathic itself is not at issue
19 here. Whether homeopathic dilution itself has activity or doesn't have
20 activity -- we're just saying we're making the homeopathic dilution, not just
21 a solvent. It has to be made from homeopathic knowledge.

22 Using it to treat the standard form, and then observing that the
23 standard form -- that does happen. It's different than it was before. The data
24 shows it. That doesn't have a particular, immediate explanation on a

1 physical level at this particular time, but experiment after experiment
2 demonstrated the reality of the effect.

3 So that shouldn't disqualify us from getting a patent even when we
4 cannot really definitely explain why this effect has occurred. The effect
5 does occur and does happen.

6 JUDGE MCCOLLUM: My concern is is it the water itself that's
7 somehow causing the agent to work better, not the homeopathic methods
8 that were used to create the solution.

9 MR. PERGAMENT: The claim excludes such possibility. The claim
10 says homeopathic medication, therapeutic dose -- a homeopathic preparation
11 prepared by homeopathic -- water would not qualify for that. It's simply
12 excluded.

13 It could not possibly try to enforce infringement on standard
14 therapeutic dose being treated with water or anything else like that. It has to
15 be treated with homeopathic dilution.

16 Moreover, the pending claims require enhanced therapeutic --

17 JUDGE MCCOLLUM: But that's sort of a product --

18 MR. PERGAMENT: -- in the form of either improved side effects or
19 improved efficacy. It requires the effect be observed in comparison with the
20 standard form -- water wouldn't do this. We certainly exclude such
21 possibility.

22 Dr. Epstein discovered a new physical phenomena. Demonstrated it
23 in a variety of models on the physical level, chemical level, biological level.
24 In biological systems this became commercially significant, that's why the
25 patent is addressed to this domain.

1 Dr. Ephstein should be able to benefit from his discovery and the data,
2 I humbly submit to the Board, is sufficient to say the discovery is not made
3 up. The data is in the file.

4 JUDGE GRIMES: I think we have your argument. Were there any
5 more questions from the panel?

6 JUDGE WALSH: No questions here. Thank you.

7 JUDGE GRIMES: Thank you for coming in this afternoon.
8 (Whereupon, the proceedings at 3:10 p.m. were concluded.)

9

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